K110204

510 (k) Summary of Safety and Effectiveness for Brainlab trauma

AUG - 5 2011

Manufacturer:

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Contact Person:	Mr. Alexander Schwiersch

Summary Date: April 18, 2011

Device:

Trade name:	Brainlab trauma
Common/Classification Name:	Brainlab Trauma, trauma 3.0, Brainlab Image Guided Surgery System / Instrument, Stereotaxic
Regulation Number:	21 CFR 882.4560
Product Code:	OLO, HAW

Predicate Device:

Modification to VectorVision Trauma (K062358)
VectorVision hip 5.1 unlimited (K083483)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II

Intended Use:

Indications For Use:

Brainlab trauma is intended to be a pre- and intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's pre- or intraoperative image data being processed by a VectorVision workstation. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a bone structure like tubular bones, pelvic, calcaneus and talus, scapula, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray or MR based model of the anatomy. In addition to the image guided navigation, Brainlab trauma also enables image-free navigation of trajectories for trauma procedures.

Example procedures include but are not limited to:

- Spinal procedures and spinal implant procedures such as pedicle screw placement.
- Pelvis and acetabular fracture treatment such as screw placement or ilio-sacral screw fixation.
- Fracture treatment procedures such as intramedullary nailing or plating or screwing, or external fixation procedures in the tubular bones.
- Retrograde drilling of osteochondral lesions

Device Description:

Brainlab trauma is intended to enable operational navigation in spinal, traumatologic surgery. It links surgical instruments tracked by passive markers to a virtual computer image space.
In Brainlab trauma this virtual computer image space refers either to intraoperatively acquired and registered x-ray images of the individual patient's bone structure or to a landmark, which is intraoperatively defined by the surgeon using the tip of a tracked instrument.
Brainlab trauma allows surgical navigation considering patient movement in correlation to calibrated surgical instruments. This allows implant positioning, screw placement and bone fracture reduction in different views and reduces the need for treatments under permanent fluoroscopic radiation.

Modifications to Predicated Device:

Besides other minor changes Brainlab trauma has changed in the following from its *Predicate Devices*:

- Introduction of a new x-ray image registration device (xSpot), which allows a free handed handling of the registration device to ensure good visibility of the device for the tracking camera.
- Introduction of trauma implant navigation on fluoro images based on an implant database for the placement of trauma implants without the need of permanent x-ray radiation.
- Multiple screw planning and navigation
- Introduction of screw fixation with the usage of a spherical drill limitation, which enables warnings of breaking out or breaking into spherical anatomical regions (e.g. acetabulofemoral joint) to prevent this breaking.
- Introduction of a x-ray image free workflow for screw fixation
- Workflow based concept for the graphical user interface including a procedure selection based on the anatomical region of interest

Verification and Validation summery

To proof conformance to the predefined specifications of Brainlab trauma and its integrated components various verification and validation tests have been performed.

Completed verification activities:

Non-clinical bench tests have been performed to ensure the correct system functionality according to its specification.

- The accuracy of the image registration using the new image registration device (xSpot) has been tested in a non-clinical setup using both plastic bones (sawbone) and cadavers.
- The x-ray image free trajectory placement has been verified regarding accuracy of depth and placement.
- The accuracy of the implant calibration has been verified to ensure the accurate implant navigation.

Moreover the complete functionalities of the system including application, subsequent subsystems and modules have been verified regarding correct behavior guided by Brainlab's design, verification/validation and risk management process. This includes:

- Part of the verification includes the testing of the workflow to ensure the correct behavior of the software.
- Detailed verification of the signed specifications covering the detailed functionality of the buttons and other was performed.
- Additionally, the measures against the defined risks of the Risk Analysis have been tested.

This strategy ensures the verification of the software algorithm, the combination of the software with the instrumentation, and the safety of the defined measures of the Risk Analysis. All tests have been successfully completed.

Completed verification activities:

Non-clinical and clinical validation have been performing to prove the usability and functionality of the overall system and certain features:

- The non-clinical validation was performed within a sawbone environment at the following features: interlocking, drill angle cone, image free workflow and the xSpot.
- Cadaver sessions have been performed to validate the workflows and the following features:
    - Image registration using the new image registration device (xSpot)
    - Implant navigation

Three clinical sites have been validating Brainlab trauma as well as new and changed features regarding a user friendly and correct functionality. Besides the clinical/software workflow all system features could be proven to be safe and effective in a clinical environment.

- The features clinically validated are:
    - The new image registration device (xSpot) in combination with the changed image acquisition functionalities including image verification
    - the x-ray image free workflow
    - The screw workflow in combination with the spherical drill limitation
    - The implant navigation
    - The semi-automatic segmentation of bone shaft fragments
    - The drill angle cone.

The verification and validation has been successfully performed. All relevant hazards have been taken into consideration and the corresponding measures are effective.

Substantial equivalence:

Brainlab trauma has been verified and validated according to Brainlab's procedures for product design and development. The information provided by Brainlab in this 510(k) application was found to be substantially equivalent with the predicate devices *Modification to VectorVision® trauma* (K062358) and (K042721), *VectorVision hip 5.1 unlimited* (K083483).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Brainlab AG
% Mr. Alexander Schwiersch
Kapellenstrasse 12
85622 Feldkirchen
Germany

Re: K110204
Trade/Device Name: Brainlab Trauma
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: July 07, 2011
Received: July 14, 2011

AUG - 5 2011

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (K110204):

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Prescription Use ____X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110204